Docket No.: 3802-090-27 CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION: Karin JOOSS et al. GROUP ART UNIT: 1632

SERIAL NUMBER: 10/807,449 EXAMINER:

FILED: March 24, 2004

FOR: CYTOKINE-EXPRESSING CELLULAR VACCINE COMBINATIONS

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

Assistant Commissioner for Patents
PO BOX 1450
ALEXANDRIA, VA 22313-1450

Sir:

Applicant(s) wish(es) to disclose the following information.

REFERENCES

■ Applicant(s) wish(es) to make of record the references listed on the attached Form PTO-1449. Copies of the listed documents are attached, where required, as are either statements of relevancy or any readily available full or partial English translations of any non-English-language documents. References AA-BC, BH-BJ and BM-CVwere filed in parent application Serial No. 10/404,662, filed April 2, 2003,

RELATED CASES

■ Attached is a list of Applicant's(s') pending applications and issued patents which may be related to the present application. Copies of the documents, where required, are attached along with Form PTO-1449.

CERTIFICATION

The undersigned certifies that

□ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application for the first time (to the knowledge of the undersigned, having made reasonable inquiry) not more than three months prior to the filing of this statement.

□ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

BASIS FOR CONSIDERATION

This Information Disclosure Statement is filed:

□ without fee and within three months of the filing date of the application.
□ without fee and within three months of the date of entry of the U.S. national stage.
■ without fee and before the mailing date of a first Office Action on the merits (to the knowledge of the undersigned).
□ without fee and with the appropriate certification above.
□ without fee and with a new CPA application.
□ without fee and with a Request for Continued Examination.
□ with fee and before the mailing date of any of a Final Office Action, Notice of Allowance or an action that otherwise closes prosecution (to the knowledge of the undersigned).
□ with fee, appropriate certification above, and before payment of the Issue Fee.

DEPOSIT ACCOUNT

■ Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to Deposit Account No. 50-1442.

Respectfully submitted,

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Form PTO 1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	DOCKET NO. 3802-090-27 CIP	SERIAL NO. 10/807,449
		APPLICANT Karin JOOSS et al.	
LIST OF REFERENCES CITED BY APPLICANT (Use Several Sheets if Necessary)		FILING DATE March 24, 2004	GROUP ART UNIT 1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	5,904,920	05/1999	Dranoff et al.			
	AB	5,078,996	01/1992	Conlon, III et al.			
	AC	5,098,702	03/1992	Zimmerman et al.			
	AD	5,225,348	07/1993	Nagata et al.			
	AE	5,266,491	11/1993	Nagata et al.			
	AF	5,436,146	07/1995	Shenk et al.			
	AG	5,637,483	06/1997	Dranoff et al.			
	AH	5,665,577	09/1997	Sodroski et al.			
	AI	5,674,486	10/1997	Sobol et al			
	AJ	5,674,704	10/1997	Goodwin et al.			
	AK	5,753,500	05/1998	Shenk et al.			
	AL	5,872,005	02/1999	Wang et al.			
	AM	5,904,920	05/1999	Dranoff et al.			
	AN	5,928,893	07/1999	Kang et al.			
	AO	5,955,331	09/1999	Danos et al.			
	AP	5,981,276	11/1999	Sodroski et al.			
	AQ	5,985,290	11/1999	Jaffee et al.			
	AR	6,033,674	03/2000	Jaffee et al.			
	AS	6,037,177	03/2000	Snyder			
	AT	6,040,183	03/2000	Ferrari et al.			
	AU	6,093,570	07/2000	Ferrari et al.			
	AV	6,210,669 B1	04/2001	Aruffo et al.			
	AW	6,303,121 B1	10/2001	Kwon			
	AX	6,350,445 B1	02/2002	Jaffee et al.			
	AY	6,355,779 B1	03/2002	Goodwin et al.			

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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U.S. PATENT DOCUMENTS

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	AZ	6,428,953 B1	08/2002	Naldini et al.			
	BA	6,458,934 B1	10/2002	Hong et al.			
	BB	6,464,973 B1	10/2002	Levitsky et al.			
	BC	6,506,604	01/2003	Finer et al.			
	BD						
	BE						
	BF						
	BG						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES	TRANSLATION NO
	BH	WO 00/72686 A1	12/07/00	WIPO	X	
	BI	WO 98/46728 A1	10/22/98	WIPO	X	
	BJ	WO 92/05262	04/02/92	WIPO	X	
✓	BK	WO99/38954	08/05/99	WIPO	X	
	BL					

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	BM	Aoki et al., "Expression of Murine Interluekin 7 in a Murine Glioma Cell Line Results in Reduced Tumorigenicity *in vivo*", Proc. Natl. Acad. Sci. USA, 89:3850-3854 (1992).
	BN	Cantrell et al., :Cloning, Sequence, and Expression of a Human Granulocyte/Macrophage Colony-Stimulating Factor", Proc. Nat'l Acad. Sci. USA, 82:6250-6254 (1985).
	BO	Chang, et al., "Immunogenetic Therapy of Human Melanoma Utilizing Autologous Tumor Cells Transduced to Secrete Granulocyte-Macrophage Colony-Stimulating Factor", Human Gene Therapy, 11:839-850 (2000).
	BP	Cryer, et al., "Cyclooxygenase-1 and Cyclooxygenase-2 Selectivity of Widely Used Nonsteroidal Anti-Inflammatory Drugs", Am. J. Med., 104: 413-421 (1998).
	BQ	Darrow, et al., "The Role of HLA Class I Antigens in Recognition of Melanoma Cells By Tumor-Specific Cytotoxic T Lymphocytes", J. Immunol., 142(9):3329-3335 (1989).

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✓ Only FOR received.

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	BR	Dranoff, et al., "Vaccination With Irradiated Tumor Cells Engineered to Secrete Murine Granulocyte-Macrophage Colony-Stimulating Factor Stimulates Potent, Specific, and Long-Lasting Anti-Tumor Immunity", Proc. Nat'l Acad. Sci. USA, 90:3539-3543 (1993).
	BS	Dummer, R., "GVAX Cell Genesys", Current Opinion in Investigational Drugs, 2(6):844-848 (2001).
	BT	Fearon, et al., Interleukin-2 Production By Tumor Cells Bypasses T Helper Function in the Generation of an Antitumor Response", Cell, 60:397-403 (1990).
	BU	Golumbek, et al., "Treatment of Established Renal Cancer By Tumor Cells Engineered to Secrete Interleukin-4", Science, 254:713-716 (1991).
	BV	Gansbacher, et al., "Interleukin 2 Gene Transfer Into Tumor Cells Abrogates Tumorigenicity and Induces Protective Immunity", J. Exp. Med., 172:1217-1224 (1990).
	BW	Gansbacher, et al., "Retroviral Vector-Mediated γ-Interferon Gene Transfer Into Tumor Cells Generates Potent and Long Lasting Antitumor Immunity", Cancer Res., 50:7820-7825 (1990).
	BX	Gri, et al.,"OX40 Ligand-Transduced Tumor Cell Vaccine Synergizes With GM-CSF and Requires CD40-Apc Signaling to Boost the Host T Cell Antitumor Response", J. Immunol., 170: 99-106 (2003).
	BY	Hock et al.,(erroneously listed in Spec as "Columbo"), "Interleukin 7 Induces CD4+ T Cell-Dependent Tumor Rejection", J. Exp. Med., 174:1291-1298 (1991)
	BZ	Hom, et al., "Common Expression of Melanoma Tumor-Associated Antigens Recognized By Human Tumor Infiltrating Lymphocytes: Analysis By Human Lymphocyte Antigen Restriction", Journal of Immunother., 10(3): 153-164 (1991).
	CA	Huebner, et al., "The Human Gene Encoding GM-CSF Is at 5q21-q32, the Chromosome Region Deleted in the 5q- Anomaly, Science 230:1282-1285 (1985).
	CB	Jaffee, et al.,"Gene Therapy: Its Potential Applications in the Treatment of Renal-Cell Carcinoma", Seminars in Oncology, 22(1):81-91 (1995).
	CC	Jaffee, et al., "Novel Allogeneic Granulocyte-Macrophage Colony-Stimulating Factor-Secreting Tumor Vaccine For Pancreatic Cancer: A Phase I Trial of Safety and Immune Activation", Journal of Clinical Oncology, 19(1):145-156 (2001).
	CD	Kawakami, et al., "Shared Human Melanoma Antigens: Recognition By Tumor-Infiltrating Lymphocytes in HLA-A2.1-Transfected Melanomas", J. Immunol., 148(2): 638-643 (1992).
	CE	Klein, et al., "Properties of the K562 Cell Line, Derived From a Patient With Chronic Myeloid Leukemia", Int. J. Cancer, 18:421-431 (1976).
	CF	Kwon, et al., "Expression Characteristics of Two Potential T Cell Mediator Genes", Cell Immunol., 121:414-422 (1989).
	CG	Kwon, et al., "cDNA Sequences of Two Inducible T-Cell Genes", Proc. Natl. Acad. Sci. USA, 86:1963-1967 (1989).

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		OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)
	CH	Lee, et al., "Genetic Immunotherapy of Established Tumors With Adenovirus-Murine Granulocyte-Macrophage Colony-Stimulating Factor", Human Gene Therapy, 8:187-193 (1997).
	CI	Lozzio, et al., "Human Chronic Myelogenous Leukemia Cell-Line With Positive Philadelphia Chromosome", Blood, 45(3):321-334 (1975).
	CJ	Melero, et al., "Monoclonal Antibodies Against the 4-1BB T-Cell Activation Molecule Eradicate Established Tumors", Nature Medicine 3(6):682-685 (1997).
	CK	Nagai, et al., "Irradiated Tumor Cells Adenovirally Engineered to Secrete Granulocyte/Macrophage-Colony-Stimulating Factor Established Antitumor Immunity and Elimate Pre-Existing Tumors in Syngeneic Mice", Cancer Immunol. Immonther., 47:72-80 (1998).
	CL	Plaksin, et al.,"Effective Anti-Metastatic Melanoma Vaccination With Tumor Cells Transfected With MHC Genes and/or Infected With Newcastle Disease Virus (NDV)", Int. J. Cancer, 59:796-801 (1994).
	CM	Porgador, et al.,"Immunotherapy of Tumor Metastasis Via Gene Therapy", Nat. Immun. 13:113-130 (1994).
	CN	Salgia, et al., "Vaccination With Irradiated Autologous Tumor Cells Engineered to Secrete Granulocyte-Macrophage Colony-Stimulating Factor Augments Antitumor Immunity in Some Patients With Metastatic Non-Small-Cell Lung Carcinoma", Journal of Clinical Oncology, 21(4): 624-630 (2003).
	CO	Salvadori, et al., "B7-1 Amplifies the Response to Interleukin-2-Secreting Tumor Vaccines *In Vivo*, but Fails to Induce a Response By Naive Cells *In Vitro*", Hum. Gene Ther., 6:1299-1306 (1995).
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	CT	Teng, et al. "Long-Term Inhibition of Tumor Growth By Tumor Necrosis Factor in the Absence of Cachexia or T-Cell Immunity", Proc. Nat'l. Acad. Sci. USA, 88:3535-3539 (1991).
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	CW	Armstrong, Ph.D., T., et al., "Cytokine Modified Tumor Vaccines", Surg. Oncol. Clin. N. Am., 11, 681-696 (2002).

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	CX	Altschul, S., et al., "Gapped BLAST and PSI-BLAST: A New Generation of Protein Database Search Programs", Nucleic Acids Res., Vol. 25, 17, 3389-3402 (1997).
	CY	Altschul, S., et al., "Basic Local Alignment Search Tool", J. Mol. Biol. 215, 403-410 (1990).
	CZ	Asher, A., et al., "Murine Tumor Cells Transduced With The Gene For Tumor Necrosis Factor-α/Evidence for Paracrine Immune Effects of Tumor Necrosis Factor Against Tumors", J. Immunol., 146, 3227-3234 (1991).
	DA	Ausubel, F., et al., "Current Protocols In Molecular Biology", Vol. 1-3, 1987 Editions.
	DB	Bergers, G., et al., "Effects of Angiogenesis Inhibitors on Multistage Carcinogenesis in Mice", Science, 284, 808-812 (1999).
	DC	Berkelhammer, J., et al., "Development Of A New Melanoma Model In C57BL/6 Mice", Cancer Res., 42, 3157-3163 (1982).
	DD	Bodey, B., et al., "Failure of Cancer Vaccines: The Significant Limitations Of This Approach To Immunotherapy", Anticancer Res., 20, 2665-2676 (2000).
	DE	Bour-Jordan, H., et al., "CTLA-4 Regulates The Requirement For Cytokine-Induced Signals in T_H2 Lineage Commitment", Nature Immunol., 4, 2, 182-188 (2003).
	DF	Freshney, R., "Animal Cell Culture, A Practical Approach" IRL Press, 1987 Edition.
	DG	Griswold, D., "Consideration Of The Subcutaneously Implanted B16 Melanoma As A Screening Model For Potential Anticancer Agents", Cancer Chemo. Reports, Part 2, Vol. 3, No. 1, 315-324 (1972).
	DH	Guo, Z., et al., "Evaluation of Promoter Strength for Hepatic Gene Expression In Vivo Following Adenovirus-Mediated Gene Transfer", Gene Therapy, 3, 802-810 (1996).
	DI	Havell, E., et al., "The Antitumor Function of Tumor Necrosis Factor (TNF)", J. Exp. Med., 167, 1067-1085 (1988).
	DJ	Hock, H., et al., "Interleukin 7 Induces CD4+ T Cell-Dependent Tumor Rejection", J. Exp. Med. 174, 1291-1298 (1991).
	DK	Hu, H-M., et al., "Development of Antitumor Immune Responses in Reconstituted Lymphopenic Hosts", Cancer Res., 62, 3914-3919 (2002).
	DL	Huang, A., et al., "Role of Bone Marrow-Derived Cells in Presenting MHC Class I-Restricted Tumor Antigens", Science, 264, 961-965 (1994).
	DM	Ill, C., et al., "Optimization of the Human Factor VIII Complementary DNA Expression Plasmid For Gene Therapy of Hemophilia A", Blood Coagulation and Fibrinolysis, Vol. 8, 2, S23-S30 (1997).
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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	DO	Kim, T-Y, et al., "Both E7 and CpG-Oligodeoxynucleotide Are Required for Protective Immunity Against Challenge With Human Papillomavirus 16 (E6/E7) Immortalized Tumor Cells: Involvement of CD4+ and CD8+ T Cells in Protection", Cancer Res., 62, 24, 7234-7240 (2002).
	DP	Kuroda, E., et al., "Sensitivity Difference to the Suppressive Effect of Prostaglandin E_2 Among Mouse Strains: A Possible Mechanism to Polarize Th2 Type Response in BALB/c Mice", J. Immunol., 164, 2386-2395 (2000).
	DQ	Mao, J., et al., "Celecoxib Modulates the Capacity for Prostaglandin E_2 and Interleukin-10 Production in Aleveolar Macrophages from Active Smokers", Clinical Cancer Research, Vol. 9, 5825-5841 (2003).
	DR	Oettgen, H., et al., "The History of Cancer Immunotherapy", Biologic Therapy of Cancer, Ch. 6, 87-119 (1991).
	DS	Remington's Pharmaceutical Sciences, 15th Edition, 1035-1038 & 1570-1580 (1975).
	DT	Rivera, V., et al., "A Humanized System for Pharmacologic Control of Gene Expression", Nature Medicine, Vol. 2, 9, 1028-1032 (1996).
	DU	Sambrook, J., et al., "Molecular Cloning A Laboratory Manual", 2nd Edition, Cold Spring Harbor Laboratory Press, Vol. 1 (1989).
	DV	Samulski, R., et al., J. Virology, "Helper-Free Stocks of Recombinant Adeno-Associated Viruses: Normal Integration Does Not Require Viral Gene Expression", Vol. 63, 9, 3822-3828 (1989).
	DW	Sawyer, T., et al., "Src Homology-2 Inhibitors: Peptidomimetic and Nonpeptide", Mini Reviews in Medicinal Chemistry, 2, 475-488 (2002).
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	DY	Ye, X., et al., "Regulated Delivery of Therapeutic Proteins After In Vivo Somatic Cell Gene Transfer", Science, 283, 88-91 (1999).
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LIST OF RELATED CASES

Docket Number	Serial or Patent Number	Filing or Issue Date	Status
3802-031-27	10/404,612	April 2, 2004	Pending
3802-040-27 CIP	5,904,920	May 18, 1999	Patented
3802-055-27 PROV	60/088,034	June 3, 1998	Abandoned
3802-056-27 CIP	09/324,707	June 2, 1999	Abandoned
3802-061-27	07/771,194	October 4, 1991	Abandoned
3802-062-27 CIP	07/956,621	October 5, 1992	Abandoned
3802-063-27 CONT	08/150,282	November 10, 1993	Abandoned
*3802-090-27 CIP	10/807,449	March 24, 2004	Pending
(Received from client)	09/612,808		

The cases listed on this Notice of Related Cases include cases which may contain information that is material to patentability. The listing of a case on this Notice should not be taken as an indication or admission that any information contained therein is material. Prior art for each case listed on this Notice may have been cited. **The files corresponding to the listed cases, which are available to the Examiner, may not have not been examined to ascertain the materiality of any prior art therein.** Accordingly, the Examiner is requested to review the file for each case listed on this Notice in order to assess the materiality of such prior art.

*Present application; listed for information.